UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

NAVEEN GUPTA, individually and on behalf of all others similarly situated, Plaintiff, v. ATHENEX, INC., RUDOLF KWAN, JOHNSON Y.N. LAU, and TIMOTHY COOK, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** Jury Trial Demanded

Plaintiff Naveen Gupta ("Plaintiff"), by and through his attorneys, alleges upon personal knowledge as to his own acts, and upon information and belief as to all other matters, based upon the investigation conducted by and through his attorneys, which included, among other things, a review of documents filed by Defendants (as defined below) with the United States Securities and Exchange Commission (the "SEC"), news reports, press releases issued by Defendants, and other publicly available documents, as follows:

NATURE AND SUMMARY OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired shares of Athenex, Inc. ("Athenex" or the "Company") common stock between August 7, 2019 and February 26, 2021, inclusive (the "Class Period"). This action is brought on behalf of the Class for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a) and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

2. Athenex was founded in 2003, and according to its recent public statements, is a "global clinical stage biopharmaceutical company dedicated to becoming a leader in the discovery, development, and commercialization of next generation drugs for the treatment of cancer." Athenex is "organized around three platforms, including an Oncology Innovation Platform, a Commercial Platform, and a Global Supply Chain Platform." One of the Company's main drug candidates is an oral paclitaxel and encequidar for the treatment of metastatic breast cancer.

3. Athenex shares trade on the NASDAQ stock exchange. Athenex is headquartered in Buffalo, New York.

4. On August 7, 2019, Athenex announced topline data showing that oral paclitaxel and encequidar met the primary efficacy endpoint with statistically significant improvement over IV paclitaxel in a Phase 3 pivotal study in metastatic breast cancer. In this release, the Company stated that it intended to seek a pre-NDA meeting with the FDA and would "be preparing our NDA submission as soon as possible." Over the next several months, Defendants continued to laud their Phase 3 study of oral paclitaxel plus encequidar.

5. On September 1, 2020, the Company announced that the FDA had accepted for filing Athenex's New Drug Application ("NDA") for Oral Paclitaxel and Encequidar in metastatic breast cancer with priority review.[1] In this release, Athenex announced that the FDA had set a target action date of February 28, 2021 for the Company's NDA, and that "the FDA has communicated that it is not currently planning to hold an advisory committee meeting to discuss the application."

6. Then on December 9, 2020, Athenex announced that it had presented updated Phase 3 data on survival and tolerability associated with Oral Paclitaxel and Encequidar in patients with

[1] https://ir.athenex.com/news-releases/news-release-details/athenex-announces-fda-acceptance-filing-us-nda-oral-paclitaxel.

metastatic breast cancer.[2] The Company announced that it had presented this Phase 3 data at the 2020 San Antonio Breast Cancer Symposium, and that the data "demonstrat[ed] clinical benefits in efficacy and tolerability of oral paclitaxel versus IVP in patents with metastatic breast cancer . . . . The findings further support the superiority of increased ORR observed with oral paclitaxel." In this announcement, Defendant Lau, Athenex's Chairman and Chief Executive Officer, stated:

> Having previously presented superior efficacy on overall response rate and favorable tolerability versus IV paclitaxel at [San Antonio Breast Cancer Symposium] 2019, it is gratifying to report that our pivotal Phase 3 trial continues to show sustained efficacy and manageable adverse events with oral paclitaxel and encequidar . . . . The updated Phase 3 PFS and OS data further support the clinical rationale for oral paclitaxel as an efficacious and tolerable treatment option for people living with metastatic breast cancer.

7. Before the markets opened on March 1, 2021, however, Athenex issued a press release entitled "Athenex Receives FDA Complete Response Letter for Oral Paclitaxel Plus Encequidar for the Treatment of Metastatic Breast Cancer."[3] In this release, Athenex noted that the "FDA Issues a CRL to indicate that the review cycle for an application is complete and that the application is not ready for approval in its present form." This release further provided that "[i]n the CRL, the FDA indicated its concern of safety risk to patients in terms of an increase in neutropenia-related sequalae on the Oral Paclitaxel arm compared with the IV paclitaxel arm."

8. In this March 1, 2021 press release, Athenex further stated that the "FDA also expressed concerns regarding the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by blinded independent centra review (BICR). The [FDA] stated that the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR."

---

[2] https://ir.athenex.com/news-releases/news-release-details/athenex-presents-updated-phase-3-data-survival-and-tolerability.

[3] https://ir.athenex.com/news-releases/news-release-details/athenex-receives-fda-complete-response-letter-oral-paclitaxel.

9. Last, in this release, Athenex wrote that the FDA "recommended that Athenex conduct a new adequate and well-conducted clinical trial in a patient population with metastatic breast cancer representative of the population of the U.S. The [FDA] determined that additional risk mitigation strategies to improve toxicity, which may involve dose optimization and / or exclusion of patients deemed to be at a higher risk of toxicity, are required to support potential approval of the NDA."

10. On this news, the price of Athenex's shares plummeted from their February 26, 2021 closing price of $12.10 per share to a March 1, 2021 close of just $5.46 each. This represents a one-day[4] drop of approximately 55%, representing hundreds of millions of dollars in lost market capitalization.

11. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the data included in the Oral Paclitaxel plus Encequidar NDA presented a safety risk to patients in terms of an increase in neutropenia-related sequalae; (ii) the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by BICR; (iii) the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR; (iv) that the Company's Phase 3 study that was used to file the NDA was inadequate and not well-conducted in a patient population with metastatic breast cancer representative of the U.S. population, such that the FDA would recommended a new such clinical trial; (v) as a result, it was foreseeable that the FDA would not approve the Company's NDA in its current form; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

[4] February 27 and 28, 2021 fell over the weekend.

JURISDICTION AND VENUE

12. The federal law claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, as well as under the common law.

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1331 and § 27 of the Exchange Act, 15 U.S.C. § 78aa.

14. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

15. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b), as the Company's headquarters are located within this District.

16. In connection with the acts, omissions, conduct and other wrongs in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

17. Plaintiff Naveen Gupta acquired and held shares of Athenex at artificially inflated prices during the class period, and has been damaged by the revelation of the Company's material misrepresentations and material omissions.

18. Defendant Athenex is a global clinical stage biopharmaceutical company dedicated to becoming a leader in the discovery, development, and commercialization of next generation drugs for the treatment of cancer. Shares of Athenex common stock trade on the NASDAQ stock

exchange under the ticker "ATNX." The Company's headquarters are located at 1001 Main Street, Suite 600, Buffalo, NY 14203. Athenex is incorporated under the laws of the State of Delaware.

19. Defendant Johnson Y.N. Lau is Athenex's Chief Executive Officer and Chairman of the Company's Board of Directors. He has served as the Chairman of the Board of Athenex since its inception and assumed the role of CEO in mid-2011.

20. Defendant Rudolf Kwan is Athenex's Chief Medical Officer.

21. Defendant Timothy Cook is Athenex's Senior Vice President, Global Oncology, having joined the Company in that role in July 2018.

22. Collectively, Defendants Lau, Kwan, and Cook are referred to throughout this complaint as the "Individual Defendants."

23. The Individual Defendants, because of their positions at the Company, possessed the power and authority to control the content and form of the Company's annual reports, quarterly reports, press releases, investor presentations, and other materials provided to the SEC, securities analysts, money and portfolio managers and investors, *i.e.*, the market. The Individual Defendants authorized the publication of the documents, presentations, and materials alleged herein to be misleading prior to its issuance and had the ability and opportunity to prevent the issuance of these false statements or to cause them to be corrected. Because of their position with the Company and access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

24. Athenex was originally formed under the laws of the State of Delaware in November 2003 under the name Kinex Pharmaceuticals, LLC. In December 2012, the Company

converted to a Delaware corporation, Kinex Pharmaceuticals, Inc. In August 2015, the Company restated its certificate of incorporation to change its name to Athenex, Inc.

25. According to Athenex's recent public statements, the Company is a "global clinical stage biopharmaceutical company dedicated to becoming a leader in the discovery, development, and commercialization of next generation drugs for the treatment of cancer." Athenex is "organized around three platforms, including an Oncology Innovation Platform, a Commercial Platform, and a Global Supply Chain Platform."

MATERIALLY FALSE AND MISLEADING STATEMENTS

26. The Class Period begins on August 7, 2019, when Athenex issued a press release announcing that "Oral Paclitaxel and Encequidar had a Significantly Higher Response Rate Over IV Paclitaxel in a Phase III Pivotal Study in Metastatic Breast Cancer." This release provided, in relevant part, that Athenex

> [A]nnounced topline data showing that oral paclitaxel and encequidar (Oral Paclitaxel) met the primary efficacy endpoint with statistically significant improvement over IV paclitaxel in a Phase III pivotal study in metastatic breast cancer.
>
> A total of 402 typical metastatic breast cancer patients were enrolled in a 2 to 1 ratio of Oral Paclitaxel to IV paclitaxel in the ITT population (265 in the Oral Paclitaxel group versus 137 in the IV paclitaxel group). Patient demographics were balanced in the two treatment groups. The primary efficacy endpoint was overall tumor response rate (ORR) confirmed at two consecutive timepoints using RECIST v1.1 criteria. Blinded assessments of tumor response were made by two independent radiologists and an independent adjudicator, using a computer algorithm to assign responses.
>
> Oral Paclitaxel showed a statistically significant improvement compared to IV paclitaxel on the primary efficacy endpoint, with an ORR of 36% for the Oral Paclitaxel group compared to 24% for IV paclitaxel patients based on ITT analysis ($p = 0.01$). Oral Paclitaxel also showed statistically significant improvement compared to IV paclitaxel based on other analyses on populations excluding non-evaluable patients (which would give higher response rates), with p-values ≤ 0.01 in all analyses. In addition, the results showed that the proportion of confirmed responders with a duration of response of more than 150 days was 2.5 times higher in the Oral Paclitaxel group than in the IV paclitaxel group.

Based on the data cut-off on July 25, 2019, there was a strong trend in progression-free survival (p = 0.077) favoring Oral Paclitaxel over IV paclitaxel, and a strong trend in overall survival (p = 0.11) favoring Oral Paclitaxel over IV paclitaxel. At the cut-off date, a higher proportion of patients on Oral Paclitaxel compared with IV paclitaxel remained progression-free and Athenex expects the PFS and OS trend will continue to improve upon follow-up.

In the study, the Oral Paclitaxel group had lower incidence and severity of neuropathy compared to IV paclitaxel: 57% of IV paclitaxel patients experienced neuropathy (all grades) versus 17% of Oral Paclitaxel patients, with grade 3 neuropathy observed in 8% of IV paclitaxel patients versus 1% of Oral Paclitaxel patients. The results also showed lower incidence of alopecia, arthralgia and myalgia in the Oral Paclitaxel group. The incidence of neutropenia was similar in both groups, but there were more incidents of grade 4 neutropenia and infection in the Oral Paclitaxel group. There were also more gastro-intestinal side effects in the Oral Paclitaxel group.

Dr. Rudolf Kwan, Chief Medical Officer of Athenex, stated, "This is the second successful Phase III clinical program accomplished by the clinical team this year. We are excited by the positive results in the Phase III pivotal study, demonstrating improved ORR for Oral Paclitaxel compared to IV paclitaxel across a full spectrum of analyses and lower incidence of neuropathy in the Oral Paclitaxel group. We will be preparing our NDA submission as soon as possible. We are also investigating additional indications for Oral Paclitaxel as well as combinations with other anti-cancer drugs, including biologics and immuno-oncology drugs. With a longer duration of response observed in this trial, we will look into the potential of this drug candidate in metronomic dosing and maintenance therapy. Based on these results, we will aggressively advance the other oral chemotherapy programs."

Dr. Johnson Lau, Chief Executive Officer and Chairman of Athenex, commented, "Based on the results of the Phase III study, together with the preliminary results generated in the angiosarcoma study, Athenex believes that Oral Paclitaxel has the potential to represent a new class of oral anti-cancer drugs, if approved, based on the findings from this Phase III study showing statistically significant improvement in ORR as monotherapy and longer duration of response over IV paclitaxel, as well as strong trends in improved PFS and OS in patients with metastatic breast cancer. There is also evidence of early onset of activity in angiosarcoma. Adding to this potential are the favorable safety data from this study showing lower incidence of neuropathy, which is currently a major reason for discontinuing IV paclitaxel treatment. There is a potential for Oral Paclitaxel, which is not designed to require steroid pre-medication for immunosuppression, to serve as a cornerstone in chemotherapy in combination with other small molecule anti-cancer drugs, biologics, and immuno-oncology treatment approaches, including other drug candidates in our oncology pipeline."

27. Also on August 7, 2019, the Company held a call with analysts. On this call, Defendant Lau stated "I'm pleased to provide an update on Athenex' second quarter operating results and, very importantly, to be able to share with you today the positive top line results achieved in our Phase III trial of oral paclitaxel and encequidar, also known as oral paclitaxel in metastatic breast cancer." He continued:

> [T]he highlights that our Phase III study successfully met its primary endpoint, showing a statistically significant and clinically meaningful improvement versus IV paclitaxel. We also saw evidence of potential benefits in terms of progression-free survival as well as overall survival.
>
> Taken together with oral paclitaxel's improved safety profile, which had lower incidence of neuropathy compared to IV paclitaxel, we believe, if approved, we will have a new class of anti-oral anticancer drugs with a differentiated and competitive profile.
>
> The successful outcome in this trial is a potentially transformative event for Athenex. We are currently analyzing the full dataset, but we believe that we are supportive of an NDA filing in metastatic breast cancer. We plan to request a pre-NDA meeting as soon as possible and plan to present the data at a major upcoming scientific meeting.

28. On this same call, Defendant Kwan stated: "As a reminder, we announced in January last year the FDA previously provided positive feedback to Athenex that they would accept the results of this one pivotal trial for license application in the U.S. if the primary endpoint is met. Importantly, these positive pivotal trial results add to a growing body of clinical evidence supporting oral paclitaxel and encequidar, which is characterized by high response rates and a strong safety profile."

29. On September 9, 2019, Athenex participated in a call with analysts at the Morgan Stanley Healthcare Conference. On this call, Defendant Lau stated: "NDA, pre-NDA meeting will occur very soon. NDS is scheduled to be early next year for submission. Everything is on track. I think one thing I'm very proud of our team is that everything that we put forward in the last many

years with regard to time line, we actually delivered everything according to time line. We will be able to deliver NDA on schedule."

30. On November 7, 2019, Athenex issued a press release on Form 8-K with the SEC announcing third quarter 2019 financial results and providing a corporate update. In this release, the Company stated that the anticipated NDA submission for Oral Paclitaxel was "on track."

31. In the Form 10-Q that this press release accompanied, Athenex wrote:

> In August 2019, we announced topline data showing that oral paclitaxel and encequidar ("Oral Paclitaxel") met the primary efficacy endpoint with statistically significant improvement over IV paclitaxel in a Phase III pivotal study in metastatic breast cancer.
>
> A total of 402 typical metastatic breast cancer patients were enrolled in a 2 to 1 ratio of Oral Paclitaxel to IV paclitaxel in the intent-to-treat ("ITT") population (265 in the Oral Paclitaxel group versus 137 in the IV paclitaxel group). Patient demographics were balanced in the two treatment groups. The primary efficacy endpoint was overall tumor response rate (ORR) confirmed at two consecutive timepoints using RECIST v1.1 criteria. Blinded assessments of tumor response were made by two independent radiologists and an independent adjudicator, using a computer algorithm to assign responses.
>
> Oral Paclitaxel showed a statistically significant improvement compared to IV paclitaxel on the primary efficacy endpoint, with an ORR of 36% for the Oral Paclitaxel group compared to 24% for IV paclitaxel patients based on ITT analysis ($p = 0.01$). Oral Paclitaxel also showed statistically significant improvement compared to IV paclitaxel based on other analyses on populations excluding non-evaluable patients (which would give higher response rates), with p-values ≤ 0.01 in all analyses. In addition, the results showed that the proportion of confirmed responders with a duration of response of more than 150 days was 2.5 times higher in the Oral Paclitaxel group than in the IV paclitaxel group.
>
> Based on the data cut-off on July 25, 2019, there was a strong trend in progression-free survival ($p = 0.077$) favoring Oral Paclitaxel over IV paclitaxel, and a strong trend in overall survival ($p = 0.11$) favoring Oral Paclitaxel over IV paclitaxel. At the cut-off date, a higher proportion of patients on Oral Paclitaxel compared with IV paclitaxel remained progression-free.
>
> In the study, the Oral Paclitaxel group had lower incidence and severity of neuropathy compared to IV paclitaxel: 57% of IV paclitaxel patients experienced neuropathy (all grades) versus 17% of Oral Paclitaxel patients, with grade 3 neuropathy observed in 8% of IV paclitaxel patients versus 1% of Oral Paclitaxel

> patients. The results also showed lower incidence of alopecia, arthralgia and myalgia in the Oral Paclitaxel group. The incidence of neutropenia was similar in both groups, but there were more incidents of grade 4 neutropenia and infection in the Oral Paclitaxel group. There were also more gastro-intestinal side effects in the Oral Paclitaxel group.

32. Also on November 7, 2019, the Company held a call with analysts to discuss the third quarter 2019 financial results. On this call, Defendant Kwan stated:

> We are moving ahead confidently towards our first NDA submission for our oral discovery platform based on the strong data we previously reported for our lead candidate, oral paclitaxel and encequidar. As a reminder, the randomized multicenter study involved 402 patients and compared our product to intravenous paclitaxel in patients with confirmed metastatic breast cancer and for whom paclitaxel monotherapy is recommended.
>
> We were very excited to announce that the study met its primary endpoint, showing statistically significant improvement over IV paclitaxel in confirmed overall tumor response rate based on ITT analysis, oral paclitaxel showed an overall response rate of 36% compared to 24% for IV paclitaxel patients. This endpoint was based on the RECIST 1.1 criteria with a p-value of 0.01. There was also benefit in terms of duration of response.
>
> As we detailed on our last call, we also saw strong trends for both progression-free survival and overall survival that favored oral paclitaxel. We are also very pleased with the safety profile for oral paclitaxel. In particular, we saw a much lower neuropathy compared to IV paclitaxel, 17% versus 57% overall, and for grade free neuropathy, 1% versus 8%. Neuropathy is the major dose limiting toxicity for IV paclitaxel treatment and can be chronic and irreversible.
>
> Collectively, the results of this pivotal study represent an important milestone in the development of this new class of oral anti-cancer drugs. Based on the Phase III results, we see compelling evidence in terms of the efficacy and safety of oral paclitaxel's clinical benefit for patients with metastatic breast cancer. We believe it will be competitive and has the potential to become a cornerstone in the treatment of metastatic breast cancer.
>
> As we disclosed, we are scheduled to deliver an oral presentation of our Phase III results at the San Antonio Breast Cancer Symposium on December 13. We plan to share additional information around the top line efficacy and safety results that we reported in August. We believe the physician community will find the data compelling and look forward to this important update.

> In the meantime, we are currently working diligently to complete our NDA submission for oral paclitaxel, which we currently expect in the first quarter of next year. We expect to provide another update after the NDA has been filed.

33. On December 13, 2019, Athenex announced "Superior Response and Survival with Lower Neuropathy of a Novel Oral Paclitaxel versus IV Paclitaxel in Treatment of Metastatic Breast Cancer." This release provided, in relevant part, that Athenex was going to present these results an oral presentation at the 2019 San Antonio Breast Cancer Symposium. In this press release, Defendant Kwan stated:

> Oral paclitaxel and encequidar is the first oral taxane to demonstrate in a Phase III study statistically significant improvement in response rate and median overall survival compared to IV paclitaxel, in the treatment of metastatic breast cancer while associated with a much lower incidence and severity of neuropathy. We believe these data suggest the potential for oral paclitaxel and encequidar to provide an important advance in the management of patients with metastatic breast cancer.

34. Also on December 13, 2019, Athenex published a copy of its presentation from the San Antonio Breast Cancer Symposium entitled "Oral paclitaxel with encequidar (OPE): The first orally administered paclitaxel shown to be superior to IV paclitaxel on confirmed response and survival with less neuropathy: A Phase III clinical study in metastatic breast cancer."[5] In this presentation, Athenex represented that the Primary Objectives of the study were: (1) "Efficacy Endpoint (Prescribed mITT Population)," with a "Confirmed tumor response by week 19," which was confirmed by "Blinded and adjudicated central independent review," and (2) "Safety and Tolerability." The presentation further detailed the "Patient Selection and Analysis Populations" used in the study.

35. In conclusion, this presentation provided that "Oral paclitaxel and encequidar is the first oral taxane in a Phase III trial to demonstrate a significant improvement in confirmed overall response rate compared to IV paclitaxel." It further noted that "oral paclitaxel and encequidar was

[5] https://www.sec.gov/Archives/edgar/data/1300699/000119312519313917/d837714dex991.htm.

associated with improved overall survival in the modified intent-to-treat population," and "was associated with a lower incidence of neuropathy and alopecia." In sum, Athenex stated that "Oral paclitaxel and encequidar provides an important oral therapeutic option for patients with metastatic breast cancer, representing a meaningful improvement in the clinical profile of paclitaxel."

36. On February 27, 2020, Athenex issued a press release announcing its fourth quarter and full year 2019 financial results and providing a corporate update. In this release, Athenex reported that "Oral Paclitaxel NDA submission is on track; Final FDA meeting scheduled for early April." This release further provided that the "[r]esults presented at 2019 San Antoni Breast Cancer Symposium . . . showed that Oral Paclitaxel had superior response and overall survival benefit compared to IV paclitaxel in the treatment of metastatic breast cancer," and that "[i]ncidence and severity of neuropathy were less frequent with Oral Paclitaxel compared to IV paclitaxel."

37. Also on February 27, 2020, Athenex held an earnings call with analysts to discuss its fourth quarter and full year 2019 financial results. On this call, Defendant Lau stated:

> We are delighted to share that we have already submitted an NDA to the FDA. We will share more information once we have confirmation that the application has been accepted. Our partner, Almirall, is responsible for the regulatory filing in Europe and will be managing commercial activities in both the U.S. and Europe.
>
> The planned NDA submission for oral paclitaxel is supported by a strong clinical data package, including the results of our Phase III trial in metastatic breast cancer completed in 2019. This trial successfully met its primary efficacy end point, showing a statistically significant improvement on overall response rate for oral paclitaxel compared to IV paclitaxel. We'll provide an update on the trial at the San Antonio Breast Cancer Symposium in December, also announcing in the conference that oral paclitaxel demonstrated a significant improvement in overall survival.
>
> I would note that this is the first oral taxane to demonstrate a significant improvement in response rate and overall survival in a Phase III study with much less neuropathy. We are on track to submit a NDA in the U.S. for oral paclitaxel.

38. On April 9, 2020, Athenex announced that it "recently participated in a constructive

meeting with the [FDA] as scheduled, to discuss the clinical section of the [NDA] for oral paclitaxel and encequidar for the treatment of metastatic breast cancer. The Company is on track to submit the NDA in accordance with the FDA's guidance, and will provide a further update when the FDA's official response to the filing becomes available."

39. On May 7, 2020, Athenex issued a press release announcing financial results for the first quarter of 2020, ended March 31, 2020, and providing a corporate update. In his release, Defendant Lau stated that "the NDA for Oral Paclitaxel is on track to be submitted soon," stating that the product had a "strong clinical data package[s]."

40. Also on May 7, 2020, the Company held an earnings call with analysts to discuss Athenex's first quarter 2020 financial results. On this call, Defendant Kwan stated that pre-NDA filing "meeting [with the FDA] was very constructive, and we did receive the meeting minutes, and the submission is on track based on the feedback the FDA provide [sic] to us." He continued:

> Our NDA submission for oral paclitaxel is imminent. We had a productive FDA meeting in early April, where we discussed our clinical package. We have been in active dialogue with the agency, and this meeting represent one of the final steps as we prepare for submission. We will provide an update on the FDA's official response when the submission becomes available.
>
> In our meeting with the FDA, the agency also provided us with guidance on further assessment of survival endpoints, and we will communicate further when it's appropriate. In addition to the strong clinical data seen in the Phase III study of Oraxol in metastatic breast cancer, we have several ongoing studies of oral paclitaxel in additional indications, including combinations.

41. On August 6, 2020, Athenex held a call with analysts to discuss the Company's second quarter 2020 financial results. On this call, Defendant Lau stated:

> Regarding the NDA for oral paclitaxel, we will be picking the same approach as we did with tirbanibulin ointment and plan to make an official announcement, once the filling has been accepted by the FDA. We are obviously pleased here with the excellent work conducted by our clinical and regulatory teams and the execution on both of these products. We look forward to providing a further update soon. Our commercial team is putting all the key elements in place for successful oral

> paclitaxel launch. Our goal as we have preciously said, is to make oral paclitaxel be chemotherapy of choice for metastatic breast cancer. And we hope to build on the success of this initial indication that expands into the compelling opportunities that exist in other cancer. Mr. Tim Cook, our head of marketing will provide further details on our commercial initiative later on in this call. We have strengthened our balance sheet through additional financings. Use of proceeds will include the commercial launch of oral paclitaxel as well as ongoing pipeline development and manufacturing infrastructure. Having the strong balance sheet is important in providing the financial flexibility to further invest in the life cycle management of oral paclitaxel and additional R&D activities in order to maximize the potential value of our product pipeline. Dr. Rudolf Kwan will provide more details on this shortly. Our specialty pharma business is performing and we reported today, record $40.2 million in revenue from product sales in the second quarter, an increase of 82% year-over-year, this represents our highest quarterly product sales to date, as a result we're raising our product sales guidance for this full year 2020 to at least mid-teen percentage growth year-over-year from $80.5 million in 2019.

42. Next, on September 1, 2020, Athenex issued a press release announcing that the FDA had accepted for filing the Company's U.S. NDA for Oral Paclitaxel and Encequidar in metastatic breast cancer with priority review. This release provided that:

> [Athenex] announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's New Drug Application (NDA) for oral paclitaxel and encequidar (Oral Paclitaxel) for the treatment of metastatic breast cancer and has granted the application Priority Review. The FDA grants Priority Review to applications for potential drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications[1]. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of February 28, 2021. Additionally, the FDA has communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.
>
> "We are working diligently with the FDA on this Priority Review to bring Oral Paclitaxel to patients with metastatic breast cancer as quickly as possible," said Dr. Rudolf Kwan, Chief Medical Officer of Athenex. "Intravenous (IV) Paclitaxel is a foundational chemotherapy in multiple tumor types and we plan to invest in broadening the label and uses for Oral Paclitaxel."
>
> Dr. Johnson Lau, Chairman and Chief Executive Officer of Athenex, also stated, "We are delighted to have achieved this major milestone for Athenex. We continue to finalize our commercial preparations to ensure a successful launch of Oral Paclitaxel, if approved. We see Oral Paclitaxel as a potentially important alternative to IV infusions, especially during the current pandemic, as it may allow cancer

> patients to take the oral chemotherapy at home. We believe the Oral Paclitaxel program validates our broader Orascovery platform, and we are committed to applying the technology to convert other IV chemotherapies into oral agents."
>
> The Oral Paclitaxel NDA submission is supported by data from a single pivotal Phase III study of Oral Paclitaxel for the treatment of metastatic breast cancer. The study is a randomized, controlled clinical trial designed to compare the safety and efficacy of Oral Paclitaxel monotherapy versus IV paclitaxel monotherapy. As previously reported, the study achieved its primary endpoint showing statistically significant improvement in overall response rate, along with a lower neuropathy, for Oral Paclitaxel compared to IV Paclitaxel.

43. One week later, on September 8, 2020, Athenex published a presentation as an attachment to a Form 8-K filing with the SEC.[6] In this presentation, Athenex said that its NDA submission was "based on data from Phase III pivotal study – a randomized, controlled clinical trial designed to compare the safety and efficacy of Oral Paclitaxel monotherapy versus IV Paclitaxel monotherapy for the treatment of metastatic breast cancer." This presentation further provided that this study "Met Primary ORR Endpoint," meaning that it had "Statistically Significant Improvement in ORR Compared to IV Paclitaxel."

44. Also on September 8, 2020, Athenex participated in a Special Call with analysts. On this call, Defendant Kwan stated:

> I'm extremely delighted to report that the NDA for oral paclitaxel has been accepted for filing by the U.S. FDA. The application has been granted priority review and assigned a PDUFA target action date of February 28, 2021. Priority review, as a reminder, is granted to applications for potential therapies that, if approved, would be significant improvements in the safety or effectiveness of the treatment when compared to standard applications. In addition, the FDA indicated in its letter that it does not currently plan to hold an Advisory Committee meeting. We are very pleased with the outcome and look forward to continue working closely with the agency in the review process. This submission is supported by a single Phase III pivotal trial, comparing the safety and efficacy of oral paclitaxel head-to-head with IV paclitaxel.
>
> I would like to quickly recap some of the positive highlights from our Phase III study. We presented the data at the 2019 San Antonio Breast Cancer Symposium. The study met its primary endpoint, showing that oral paclitaxel had a statistically

[6] https://www.sec.gov/Archives/edgar/data/1300699/000119312520240630/d21816dex992.htm.

> significant improvement in overall response rate compared to IV paclitaxel. We show here the responses for both ITT as well as prespecified modified ITT populations, both of which were statistically significant. Importantly, we also demonstrated an overall survival benefit in the mITT population with a median of 27.9 months for oral paclitaxel versus 16.9 months for IV paclitaxel, an impressive 11-month improvement, which was statistically significant.

45. Also on this September 8, 2020 call, Defendant Lau stated: "[w]ith clinical success demonstrated and an NDA now filed in the first indication, we believe the development and regulatory risks have been largely mitigated."

46. Moreover, on September 8, 2020, Athenex filed a Prospectus on Form 424B5 with the SEC announcing its intent to sell 10 million shares of the Company's common stock, pursuant to a previously-filed shelf registration statement. In this Prospectus, the Company stated:

> On September 1, 2020, we announced that the U.S. Food and Drug Administration (FDA) has accepted for filing our New Drug Application (NDA) for Oral Paclitaxel for the treatment of metastatic breast cancer ("MBC"), and has granted the application Priority Review. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of February 28, 2021. Additionally, the FDA has communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.
>
> We announced topline results in August 2019 for our Phase 3 study of Oral Paclitaxel for the treatment of MBC and presented further data of the Phase 3 study in an oral presentation at the 2019 San Antonio Breast Cancer Symposium, or SABCS, in December 2019. Results demonstrated that the study met its primary endpoint showing statistically significant improvement in overall response rate for Oral Paclitaxel compared to intravenous ("IV") paclitaxel and neuropathy was less frequent with Oral Paclitaxel compared to IV paclitaxel. In addition, ongoing analysis of secondary endpoints of survival showed a strong trend favoring Oral Paclitaxel. In particular, Oral Paclitaxel showed a statistically significant improvement in overall survival compared to IV paclitaxel in the prespecified modified intention-to-treat population.

47. Two days later, on September 10, 2020, Athenex announced that it was offering 10 million shares at $11.00 each in this public offering, and further granted the underwriters a 30-day option to purchase up to an additional 1.5 million shares at $11.00 each.

48. On November 5, 2020, Athenex reported its financial results for its third quarter of 2020, ended September 30, 2020. In a press release attached to a Form 8-K filed with the SEC, Athenex reiterated that the "FDA accepted and granted priority review of NDA for Oral Paclitaxel in metastatic breast cancer," and highlighted how the Company had "[f]our abstracts featuring Oral Paclitaxel . . . accepted for presentation at the San Antonio Breast Cancer Virtual Symposiums, to take place December 8-11, 2020."

49. In this November 5, 2020 release, Defendant Lau stated:

> Our New Drug Application (NDA) filing for Oral Paclitaxel was accepted with priority review and a target action date of February 28, 2021 . . . . Oral Paclitaxel has a compelling efficacy, and tolerability profile that we believe positions it to potentially become the chemotherapy of choice in metastatic breast cancer. Our supply chain is in place and we are finalizing our commercial plans, with the goal of launching in the U.S. upon approval in the first quarter of 2021.

50. Also on November 5, 2020, Athenex held a call with analysts to discuss its third quarter financial results. On this call Defendant Kwan stated: "the NDA for Oral Paclitaxel was accepted by the FDA and assigned a PDUFA target action date of February 28, 2021. Ongoing dialogue with the FDA is encouraging and we are pleased with our progress to date."

51. On this same November 5, 2020 call, Defendant Cook stated:

> The final stages of commercial planning for Oral Paclitaxel are underway. The company is prepared to launch immediately upon the FDA action date of February 28, 2021 or earlier. Let me recap our progress.
>
> Our medical science liaison team is in place and is engaging in scientific discussions with key opinion leaders. Our nurse oncology educators are on board and will provide information on dosing and managing side effects to the oncology treatment teams upon launch. In the meantime, the team will begin profiling its local territories and start having unbranded discussions around the disease state and patient care.
>
> We have hired 2 national account directors to engage with the payer community during the third quarter. Based on the Preapproval Information Exchange Act or PIE, the account managers may target payers establishing policy at a national level ahead of drug approval. Activities focused on educating these customers about

health care economic information pertaining to Oral Paclitaxel in order to facilitate coverage decisions and budget allocations. Athenex is in the process of hiring 5 corporate account directors to cover smaller regional payers and large integrated delivery networks like Kaiser.

Our last step involves onboarding our sales representatives in the December-January time frame ahead of our expected launch. In parallel, we are wrapping up our work on the value proposition of Oral Paclitaxel to the payer community and finalizing our pricing and contracting strategy. Feedback has been overwhelmingly positive as payers view our drug as innovative, which is in line with our prior pricing assumptions. Contracts are in place with all key distributors and specialty pharmacies, and our distribution model is finalized.

Developing patient outreach initiatives remain a key focus. Our patient support program is near completion. An additional point of contact is created in the specialty pharmacy hub to help manage both treatment and reimbursement as well as to provide a financial assisted system for patients.

October was breast cancer awareness month. Athenex has been very active and focused on amplifying its share of voice and visibility around breast cancer through the month. The company launched a guide to facing metastatic breast cancer on October 9 and held a virtual media tour featuring Dr. Beth DuPree, which consisted of TV and radio interviews accompanied by social media post across multiple platforms.

Core marketing messages to be used by our sales force are in the final stages of development. Our market research shows that our messages around efficacy and the first oral taxane resonate well. Physicians are responding positively to the safety language around neuropathy, no need to pre-medicate patients and a lack of infusion reactions.

We will have a presence at the San Antonio Breast Cancer Symposium. In addition to the 4 abstracts that Rudolf mentioned, we will also have a virtual exhibit. Lastly, we finalized the brand campaign for Oral Paclitaxel that will roll out after launch.

To summarize, we are ready to launch Oral Paclitaxel upon approval. Payer outreach has begun and we have prepared initiatives targeting physicians, office staff and patients. Additionally, we are planning several virtual physician outreach events that can be rapidly deployed upon approval to promote the drug.

52. On December 9, 2020, Athenex issue a press release presenting "Updated Phase 3 Data on Survival and Tolerability Associated with Oral Paclitaxel and Encequidar in Patients with Metastatic Breast Cancer." The Company announced that data presented at the 2020 San Antonio

Breast Cancer Symposium "indicate[s] benefits of oral paclitaxel and encequidar . . . versus IV paclitaxel (IVP) on Progress-Free Survival (PFS) and on Overall Survival (OS), which supports superiority on the primary endpoint Overall Response Rate (ORR)."

53. In this December 9, 2020 release, Athenex announced:

> The findings further support the superiority of increased ORR observed with oral paclitaxel. These data were presented today during a spotlight poster presentation at the 2020 San Antonio Breast Cancer Symposium (SABCS).
>
> "Having previously presented superior efficacy on overall response rate and favorable tolerability versus IV paclitaxel at SABCS 2019, it is gratifying to report that our pivotal Phase 3 trial continues to show sustained efficacy and manageable adverse events with oral paclitaxel and encequidar," said Dr. Johnson Lau, Chairman and Chief Executive Officer of Athenex. "The updated Phase 3 PFS and OS data further support the clinical rationale for oral paclitaxel as an efficacious and tolerable treatment option for people living with metastatic breast cancer."
>
> The spotlight poster presentation at SABCS featured an update on PFS and OS data from the Phase 3 trial. In the prespecified modified intent-to-treat (mITT) population (n = 360), the median PFS data showed a benefit for oral paclitaxel versus IVP (8.4 vs. 7.4 months, respectively; hazard ratio [HR] = 0.739; 95% confidence interval [CI]: 0.561, 0.974; p = 0.023). Median OS data also showed a benefit for oral paclitaxel versus IVP (23.3 months vs. 16.3 months, respectively; HR = 0.735; 95% CI: 0.556, 0.972; p = 0.026).
>
> In the intent-to-treat (ITT) population, which included all 402 randomized patients, the median PFS showed a benefit for oral paclitaxel versus IVP (8.4 months vs. 7.4 months, respectively; HR = 0.768; 95% CI: 0.584, 1.01; p = 0.046). The median OS data demonstrated a trend favoring oral paclitaxel versus IVP (22.7 months vs. 16.5 months, respectively; HR = 0.794; 95% CI: 0.607, 1.037; p = 0.082).
>
> Updated safety analyses of up to 112 weeks continue to demonstrate the reduction in incidence and severity of neuropathy favoring oral paclitaxel versus IVP: all grades of neuropathy were 22% vs. 64%, and grade 3 neuropathy was 2% vs. 15%. Also presented were data on the effect of prophylactic treatments on the incidence and severity of gastrointestinal-related adverse events. After approximately 30% of patients were enrolled, the Phase 3 trial protocol was amended to allow patients randomized to the oral paclitaxel arm to receive prophylactic pre-medications for gastrointestinal side effects. Overall gastrointestinal (GI)-related adverse events (AEs) were less frequent in the IV paclitaxel arm. GI-related AEs improved in the oral paclitaxel arm following the amendment, as measured by lower incidences of grade 2 vomiting before and after amendment (24% vs. 7%) and grade 2 diarrhea before and after amendment (27% vs. 16%).

> "The oral paclitaxel regimen appears to overcome some of the limitations of IV therapy, particularly in terms of reducing the risk of neuropathy," commented lead investigator Gerardo Antonio Umanzor Fúnez, M.D., a medical oncologist at Centro Oncologico Integral, working with DEMEDICA of San Pedro Sula, Honduras. "The lessened burden of neuropathy, the ability to manage GI side effects with prophylactic treatments, and the convenience of home-based administration, could be transformational in the treatment of metastatic breast cancer, especially in the current environment."
>
> Oral paclitaxel has been granted Priority Review by the U.S. Food and Drug Administration (FDA) for the treatment of metastatic breast cancer with a PDUFA date of February 28, 2021.
>
> **About the Phase 3 Oral Paclitaxel and Encequidar Clinical Trial**
>
> The Phase 3 trial randomized 402 patients with any metastatic breast cancer subtypes in a 2:1 ratio to receive either the oral paclitaxel regimen (205 mg/m^2 of oral paclitaxel plus 15 mg of encequidar) for three days a week or the approved IV paclitaxel regimen (175 mg/m^2) as a three-hour infusion every three weeks. The primary efficacy endpoint was overall response rate (ORR) confirmed at two consecutive timepoints by a blinded, independent radiology review that used RECIST v1.1 criteria to evaluate patients' tumors for response. The trial was designed to demonstrate superiority of oral paclitaxel over IVP on the primary end point of ORR. Secondary endpoints included progression-free survival (PFS) and overall survival (OS). The trial was not powered to demonstrate superiority of oral paclitaxel versus IVP on the secondary survival endpoints of PFS and OS. These secondary endpoints were not controlled for multiplicity. P-values presented are nominal.

54. The statements identified above were materially false and misleading and failed to disclose material facts about the Company's business, operations, and prospects. As discussed below, the Defendants misled investors by misrepresenting and omitting to disclose that: (i) the data included in the Oral Paclitaxel plus Encequidar NDA presented a safety risk to patients in terms of an increase in neutropenia-related sequalae; (ii) the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by BICR; (iii) the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR; (iv) that the Company's Phase 3 study that was used to file the NDA was inadequate and

not well-conducted in a patient population with metastatic breast cancer representative of the U.S. population, such that the FDA would recommended a new such clinical trial; (v) as a result, it was foreseeable that the FDA would not approve the Company's NDA in its current form; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

55. The statements described in ¶¶ 26-53 were materially false and misleading and failed to disclose material adverse facts about the Company's business, operations, and prospects.

THE TRUTH EMERGES

56. Before the markets opened on March 1, 2021, Athenex issued a press release entitled "Athenex Receives FDA Complete Response Letter for Oral Paclitaxel Plus Encequidar for the Treatment of Metastatic Breast Cancer." In this release, Athenex noted that the "FDA Issues a CRL to indicate that the review cycle for an application is complete and that the application is not ready for approval in its present form." This release further provided that "[i]n the CRL, the FDA indicated its concern of safety risk to patients in terms of an increase in neutropenia-related sequalae on the Oral Paclitaxel arm compared with the IV paclitaxel arm."

57. In this March 1, 2021 press release, Athenex further stated that the "FDA also expressed concerns regarding the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by blinded independent centra review (BICR). The [FDA] stated that the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR."

58. Further, Athenex wrote that the FDA "recommended that Athenex conduct a new adequate and well-conducted clinical trial in a patient population with metastatic breast cancer representative of the population of the U.S. The [FDA] determined that additional risk mitigation

strategies to improve toxicity, which may involve dose optimization and / or exclusion of patients deemed to be at a higher risk of toxicity, are required to support potential approval of the NDA."

59. Also on March 1, 2021, before the markets opened, Athenex issued a press release announcing fourth quarter and full year 2020 financial results.[7] In this release, the Company reiterated that in its Complete Response Letter, the FDA expressed: (1) "[c]oncerns about safety risks associated with increase in neutropenia-related sequelae"; (2) "[c]oncerns about the primary endpoint assessment conducted by the Blinded Independent Central Review (BICR)"; and (3) "[r]ecommendation that Athenex conduct a new clinical trial in a patient population with metastatic breast cancer representative of the population in the U.S."

60. In this release, Defendant Lau stated: "[b]ased on the clinical benefits demonstrated by the Phase III trial results, we are committed to exploring our available options to obtain approval for oral paclitaxel and encequidar. Additionally, we will undertake a thorough review of our organization to best position ourselves to create value for all stakeholders as we move forward."

61. On this news, the price of Athenex's shares plummeted from their February 26, 2021 closing price of $12.10 per share to a March 1, 2021 close of just $5.46 each. This represents a one-day drop of approximately 55%, or hundreds of millions of dollars in lost market capitalization.

CLASS ACTION ALLEGATIONS

62. Plaintiff brings this action as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired shares of Athenex common stock between August 7, 2019 and February 26,

[7] https://ir.athenex.com/news-releases/news-release-details/athenex-provides-fourth-quarter-and-full-year-2020-corporate-and.

2021, inclusive. Excluded from the Class are Defendants, directors and officers of the Company, as well as their families and affiliates.

63. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Throughout the Class Period, Athenex securities were actively traded on the NASDAQ stock exchange. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes there are thousands of members in the proposed Class.

64. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether Defendants violated the Exchange Act;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. Whether the price of the Company's shares was artificially inflated; and

f. The extent of damage sustained by Class members and the appropriate measure of damages.

65. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein.

66. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.

67. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

FRAUD ON THE MARKET

68. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine that, among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. The omissions and misrepresentations were material;

c. The Company's shares traded in efficient markets;

d. The misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's shares; and

e. Plaintiff and other members of the class purchased the Company's shares between the time Defendants misrepresented or failed to disclose material facts and the time that the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

69. At all relevant times, the markets for the Company's shares were efficient for the following reasons, among others: (i) the Company filed periodic public reports with the SEC; and (ii) the Company regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures such as communications with the financial press, securities analysts, and other similar reporting services. Plaintiff and the Class relied on the price of the Company's shares, which reflected all information in the market, including the misstatements by Defendants.

NO SAFE HARBOR

70. The statutory safe harbor provided for forward-looking statements under certain conditions does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as forward-looking statements when made.

71. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

LOSS CAUSATION

72. Before the markets opened on March 1, 2021, Athenex announced that the FDA had issued a Complete Response Letter indicating that the review cycle for an application is complete and that the application is not ready for approval in its present form, with the additional details as alleged herein. On this news, the price of Athenex's shares plummeted from their February 26, 2021 closing price of $12.10 per share to a March 1, 2021 close of just $5.46 each. This represents a one-day drop of approximately 55%.

73. These revelations contradicted statements made by Defendants during the Class Period, and revealed information omitted by Defendants during the Class Period, and were thus a causal element of the concurrent decline in the Company's share price.

Count One
Violations of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder
(Against All Defendants)

74. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

75. During the Class Period, Defendant Athenex and the Individual Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose

material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading.

76. Defendant Athenex and the Individual Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon those who purchased or otherwise acquired the Company's securities during the class period.

77. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's shares. Plaintiff and the Class would not have purchased the Company's shares at the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

Count Two
Violation of § 20(a) of the Exchange Act
(Against the Individual Defendants)

78. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

79. The Individual Defendants acted as controlling persons of the Company within the meaning of § 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions at the Company, the Individual Defendants had the power and authority to cause or prevent the Company from engaging in the wrongful conduct complained of herein. The Individual Defendants were provided with or had unlimited access to the documents described above that contained statements alleged by Plaintiff to be false or misleading both prior to and immediately

after their publication, and had the ability to prevent the issuance of those materials or to cause them to be corrected so as not to be misleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) determining that this action is a proper class action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a certification of Plaintiff as class representative pursuant to Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiff's counsel as Lead Counsel;

(b) awarding compensatory and punitive damages in favor of Plaintiff and the other class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon.

(c) awarding Plaintiff and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

(d) awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in this action of all issues so triable.

Dated: March 3, 2021

Respectfully submitted,

/s/ Stephen J. Teti
Stephen J. Teti
BLOCK & LEVITON LLP
260 Franklin Street, Suite 1860
Boston, MA 02110
(617) 398-5600 phone

(617) 507-6020 fax
steti@blockleviton.com

Attorney for Plaintiff and Proposed Lead Counsel